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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,575	04/14/2000	FRANCIS JAMES ROURKE	7042-R	9622

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EXAMINER

ANDERSON, CATHARINE L

ART UNIT	PAPER NUMBER
3761	

3761

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/529,575

Applicant(s)

ROURKE ET AL.

Examiner

C. Lynne Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 March 2004.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 31,32,36,41-46 and 48-53 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 31,32,36,41-46 and 48-53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 - Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 - Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 - Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 - Paper No(s)/Mail Date _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION***Claim Objections***

Claim 42 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 42 depends from claim 41, which in turn depends from claim 31. Claim 31 discloses an absorbent article comprising from 0.0001% to 30% by weight of a protease inhibitor. Claim 41 further limits the absorbent article to comprise a delivery system, the delivery system comprising the protease inhibitor. Claim 41 does not require any further components to the absorbent article, and it is within the scope of claim 41 that the absorbent article is the delivery system. Claim 42 further limits the delivery system as being a skin care composition. Therefore, if the absorbent article is the delivery system, and the delivery system is a skin care composition, the absorbent article is the skin care composition. Since claim 42 discloses the skin care composition comprises from 0.01% to 50% by weight of the protease inhibitor, claim 42 fails to further limit claim 31, and in fact broadens the scope of claim 31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 32, 36, 41-46, and 48-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cadwell (5,874,164).

With respect to claims 31, 32, and 36, Cadwell discloses all aspects of the claimed invention but remains silent as to the percent by weight of the protease inhibitor. Cadwell discloses an absorbent article, as described in column 6, lines 23-26, at least a portion of which comprises a protease inhibitor, as described in column 55, lines 16-19. The protease inhibitor is pentamidine, as described in column 55, line 28.

It would have been obvious to one of ordinary skill in the art at the time of invention to have the protease inhibitor present in the article in a range of about 0.0001% to about 30% by weight. The protease inhibitor of Cadwell is coated onto the absorbent article, as disclosed in column 56, lines 15-21, and to coat the surface of the article fully, the amount of protease inhibitor would obviously have to be greater than 0.0001% by weight. However, the surface of the article can only accommodate so much of a coating, and therefore it would also be obvious that the protease inhibitor would not be greater than 30% by weight.

The IC_{50} is defined in the instant specification on page 7 as being dependant on the concentration of protease inhibitor and the rate of substrate cleavage of the protease inhibitor. The rate of substrate cleavage is dependent on the individual protease inhibitor, and pentamidine is disclosed in the specification as being a suitable protease inhibitor. Therefore, pentamidine, when present in the claimed concentration, inherently has an IC_{50} of about 500

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μM or less, no more than $100 \mu\text{M}$, and as a result is capable of producing at least a 10% reduction in substrate hydrolysis by a protease.

With respect to claim 41, the article comprises a delivery system, a barrier web 15, as shown in figure 8, which comprises the protease inhibitor.

With respect to claims 42 and 43, the article can comprise a delivery system, a bandage or surgical gauze, as disclosed in column 53, lines 57-62, which facilitates the healing of a wounds and is therefore a skin care composition. The skin care composition comprises between about 0.0001% and about 30% of the protease inhibitor, as disclosed in the rejection of claim 31 above.

With respect to claim 44, the delivery system is a solid support.

With respect to claim 45, the delivery system is activatable by moisture and releases the protease inhibitor, as disclosed in column 55, lines 31-35.

With respect to claim 46, the deliver system contains the protease inhibitor as molecules, or particles, as disclosed in column 55, line 37.

With respect to claim 48, the article comprises a barrier web 15, as shown in figure 8, having the protease inhibitor disposed on at least a portion thereof. The barrier web 15 comes in contact with the wearer.

With respect to claim 49, the barrier web 15 is part of the waist region of the article, as shown in figure 7.

With respect to claims 50 and 51, the wearer-contacting surface may be a bandage or surgical gauze, as disclosed in column 53, lines 57-62, which is a topsheet.

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With respect to claims 52 and 53, it would have been an obvious matter of design choice for the topsheet to comprise regions that do not contain the skin care composition and have the skin care composition disposed in a plurality of stripes, since the applicant has not shown that this application of the skin care composition solves any stated problem or serves any particular purpose, and it appears the invention would perform equally well with the skin care composition disposed on all regions of the topsheet. *In re Dailey*, 140 USPQ 47.

Response to Arguments

The rejection of claims 31, 32, 36, 41-46, and 48-53 under 35 U.S.C. 103(a) as being unpatentable over Cadwell (5,874,164) based on the obviousness of optimizing the range of protease inhibitor in the absorbent article has been withdrawn. The rejection is now based on the obviousness of the absorbent article comprising the protease inhibitor in the claimed range, as described in the rejection of the claims above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (703) 306-5716. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (703) 305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLA

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July 8, 2004


JOHN S. CALVERT
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